



**IN THE CIRCUIT COURT OF  
MONTGOMERY COUNTY, ALABAMA**

**STATE OF ALABAMA,**

**Plaintiff,**

**v.**

**ABBOTT LABORATORIES, et al.,**

**Defendants.**

**CV-05-219**

**ANSWER OF DEFENDANT SANOFI-SYNTHELABO INC. TO  
THE STATE OF ALABAMA'S SECOND AMENDED COMPLAINT**

Defendant Sanofi-Synthelabo Inc. ("Sanofi"), for its Answer to the State of Alabama's Second Amended Complaint ("Complaint") in the captioned action, by its undersigned counsel, alleges upon knowledge as to itself, and upon information and belief as to all other matters, as follows:

**INTRODUCTION**

1. Denies each and every allegation set forth in paragraph 1 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
2. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 2 of the Complaint, except denies the existence of a fraudulent pricing scheme or that Sanofi is or has been involved in any such scheme.
3. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 3 of the Complaint, except admits that the State of Alabama purports to bring this action, denies that there is any basis on which to permit the State to do so, denies the existence of any "drug pricing scheme," denies that Sanofi is or has been involved in any such scheme, and denies that Sanofi has obtained any profits as a result of any such imagined scheme.
4. Denies each and every allegation set forth in paragraph 4 of the Complaint as to Sanofi, except admits that the State of Alabama purports to seek legal and equitable redress but denies there is any basis on which to permit it to do so, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

**PARTIES**

5. Admits that the State of Alabama purports to bring this action in its capacity as sovereign and on behalf of the Alabama Medicaid Agency but denies that there is any basis on which to permit it to do so.

6. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 6 of the Complaint and further respectfully refers the Court to Alabama Code § 36-15-12 for a full and complete reading of its provisions.

**Defendant Abbott**

7. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 7 of the Complaint.

**Defendant Alcon**

8. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 8 of the Complaint.

**Defendant Allergan**

9. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 9 of the Complaint.

**The Alpha Defendants**

10. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 10 of the Complaint.

11. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 11 of the Complaint.

12. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 12 of the Complaint.

**The Amgen Defendants**

13. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 13 of the Complaint.

14. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 14 of the Complaint.

15. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 15 of the Complaint.

**Defendant Andrx**

16. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 16 of the Complaint.

**The AstraZeneca Defendants**

17. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 17 of the Complaint.

18. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 18 of the Complaint.

19. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 19 of the Complaint.

**The Aventis Defendants**

20. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 20 of the Complaint.

21. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 21 of the Complaint.

22. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 22 of the Complaint.

23. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 23 of the Complaint.

**Defendant Barr**

24. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 24 of the Complaint.

**The Baxter Defendants**

25. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 25 of the Complaint.

26. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 26 of the Complaint.

27. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 27 of the Complaint.

**The Bayer Defendants**

28. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 28 of the Complaint.

29. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 29 of the Complaint.

30. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 30 of the Complaint.

31. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 31 of the Complaint.

**Defendant Biovail**

32. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 32 of the Complaint.

**The Boehringer Defendants**

33. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 33 and lettered subparagraphs a and b of the Complaint.

34. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 34 of the Complaint.

**Defendant Bristol-Myers Squibb**

35. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 35 of the Complaint.

**Defendant DEY**

36. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 36 of the Complaint.

**Defendant Eisai**

37. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 37 of the Complaint.

**Defendant Endo**

38. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 38 of the Complaint.

**Defendant ETHEX**

39. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 39 of the Complaint.

**The Forest Defendants**

40. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 40 of the Complaint.

41. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 41 of the Complaint.

42. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 42 of the Complaint.

**The Fujisawa Defendants**

43. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 43 of the Complaint.

44. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 44 of the Complaint.

45. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 45 of the Complaint.

**Defendant Genzyme**

46. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 46 of the Complaint.

**Defendant Gilead**

47. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 47 of the Complaint.

**Defendant GlaxoSmithKline**

48. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 48 of the Complaint.

**The Hoffmann-LaRoche Defendants**

49. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 49 of the Complaint.

50. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 50 of the Complaint.

51. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 51 of the Complaint.

**The IVAX Defendants**

52. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 52 of the Complaint.

53. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 53 of the Complaint.

54. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 54 of the Complaint.

**The J&J Defendants**

55. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 55 and lettered subparagraphs a through e of the Complaint.

56. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 56 of the Complaint.

**The King Defendants**

57. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 57 of the Complaint.

58. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 58 of the Complaint.

59. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 59 of the Complaint.

**Defendant MedImmune**

60. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 60 of the Complaint.

**Defendant Merck**

61. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 61 of the Complaint.

**The Mylan Defendants**

62. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 62 of the Complaint.

63. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 63 of the Complaint.

64. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 64 of the Complaint.

65. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 65 of the Complaint.

**The Novartis Defendants**

66. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 66 of the Complaint.

67. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 67 of the Complaint.

68. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 68 of the Complaint.

**Defendant Novo Nordisk**

69. Denies knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 69 of the Complaint.

**Defendant Organon**

70. Denies knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 70 of the Complaint.

**Defendant Par**

71. Denies knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 71 of the Complaint.

**The Pfizer Defendants**

72. Denies knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 72 of the Complaint.

73. Denies knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 73 of the Complaint.

74. Denies knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 74 of the Complaint.

75. Denies knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 75 of the Complaint.

76. Denies knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 76 of the Complaint.

77. Denies knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 77 of the Complaint.

**Defendant Purdue**

78. Denies knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 78 of the Complaint.

**Defendant Sanofi**

79. Admits that Sanofi-Synthelabo is the U.S. affiliate of Sanofi-Aventis, is a Delaware corporation with its principal place of business located at 90 Park Avenue, New York, NY 10016, and is engaged in the business of manufacturing, distributing, marketing, and/or selling prescription drugs. Sanofi admits that its drugs “are reimbursed by state Medicaid agencies nationwide” and that it manufactures, distributes, markets, and/or sells the prescription drugs that are reimbursed by Alabama Medicaid and which are identified in Exhibit A of the Complaint.

**The Schering Defendants**

80. Denies knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 80 of the Complaint.

81. Denies knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 81 of the Complaint.

82. Denies knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 82 of the Complaint.

**Defendant TAP Pharmaceutical**

83. Denies knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 83 of the Complaint.

**Defendant Takeda Pharmaceuticals**

84. Denies knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 84 of the Complaint.



**Defendant Teva**

85. Denies knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 85 of the Complaint.

**The Watson Defendants**

86. Denies knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 86 of the Complaint.

87. Denies knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 87 of the Complaint.

88. Denies knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 88 of the Complaint.

89. Denies knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 89 of the Complaint.

**The Wyeth Defendants**

90. Denies knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 90 of the Complaint.

91. Denies knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 91 of the Complaint.

92. Denies knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 92 of the Complaint.

**Fictitious Defendants**

93. Denies knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 93 of the Complaint.

94. Denies each and every allegation set forth in paragraph 94 of the Complaint as to Novartis, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

**JURISDICTION AND VENUE**

95. Denies each and every allegation set forth in paragraph 95 of the Complaint.

96. Denies the allegations set forth in paragraph 96 of the Complaint as to Sanofi, except to state that its products are available for sale in Alabama just as in any other state, and

otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

97. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

### **FACTUAL BACKGROUND**

#### **The Alabama Medicaid Program**

98. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 98 of the Complaint, except admits that the Alabama Medicaid Program is a state-administered program with federal matching funds which pays for medical care, including prescription drug benefits, for certain Alabama citizens.

99. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 99 of the Complaint.

100. Denies each and every allegation set forth in paragraph 100 of the Complaint as to Aventis, except admits that, from time to time during the relevant period, Aventis provided price lists to third party publications which contained pricing information, including certain pricing terminology such as “AWP” for certain of its drugs and, affirmatively states that AWP is commonly understood to be a benchmark used throughout the industry and not an average price charged by wholesalers to the entities identified in paragraph 100, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

101. Admits the allegations set forth in paragraph 101 of the Complaint.

102. Denies each and every allegation set forth in paragraph 102 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

#### **The Defendants' Reporting of Inflated Pricing Information**

103. Denies each and every allegation set forth in paragraph 103 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

104. Denies knowledge or information sufficient to form a belief about the truth of the allegations set forth in paragraph 104 of the Complaint.

105. Denies each and every allegation set forth in paragraph 105 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

106. Denies each and every allegation set forth in paragraph 106 of the Complaint as to Sanofi, except admits that Sanofi knows the WAC and Direct Price of its own products, and the AWP it listed on its price lists for its own products, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

107. Denies each and every allegation set forth in paragraph 107 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

**Defendants' Marketing of the "Spread"**

108. Denies each and every allegation set forth in paragraph 108 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

109. Denies each and every allegation set forth in paragraph 109 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

110. Denies each and every allegation set forth in paragraph 110 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

111. Denies each and every allegation set forth in paragraph 111 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

**Other Lawsuits, Settlements, Government Investigations, and Criminal Proceedings**

112. Denies each and every allegation set forth in paragraph 112 of the Complaint, except admits that other plaintiffs have filed complaints alleging similarly meritless and ill-informed claims from which Plaintiff here appears to have largely copied its allegations.

113. Denies each and every allegation set forth in paragraph 113 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein except admits that Sanofi is one of the defendants named in *The City of New York v. Abbott Laboratories, Inc.*, 04-CV-06054, in the United States District Court for the Southern District of New York (August 4, 2004), an action in which the plaintiff has made meritless and ill-founded allegations similar to those asserted in this action, and from which Plaintiff here appears to have largely copied its allegations.

114. Denies each and every allegation set forth in paragraph 114 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

115. Paragraph 115 of the Complaint appears to contain no allegations as to, or relevant to, any claims against Sanofi and therefore requires no answer; to the extent Plaintiff

purports to make allegations as to Sanofi, Sanofi denies each and every allegation set forth in paragraph 115 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

116. Paragraph 116 of the Complaint appears to contain no allegations as to, or relevant to, any claims against Sanofi and therefore requires no answer; to the extent Plaintiff purports to make allegations as to Sanofi, Sanofi denies each and every allegation set forth in paragraph 115 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties regarding other parties set forth therein.

117. Paragraph 117 of the Complaint appears to contain no allegations as to, or relevant to, any claims against Sanofi and therefore requires no answer; to the extent Plaintiff purports to make allegations as to Sanofi, Sanofi denies each and every allegation set forth in paragraph 117 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

118. Paragraph 118 of the Complaint appears to contain no allegations as to, or relevant to, any claims against Sanofi and therefore requires no answer; to the extent Plaintiff purports to make allegations as to Sanofi, Sanofi denies each and every allegation set forth in paragraph 118 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

119. Paragraph 119 of the Complaint appears to contain no allegations as to, or relevant to, any claims against Sanofi and therefore requires no answer; to the extent Plaintiff purports to make allegations as to Sanofi, Sanofi denies each and every allegation set forth in paragraph 119 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

120. Paragraph 120 of the Complaint appears to contain no allegations as to, or relevant to, any claims against Sanofi and therefore requires no answer; to the extent Plaintiff purports to make allegations as to Sanofi, Sanofi denies each and every allegation set forth in paragraph 120 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

121. Paragraph 121 of the Complaint appears to contain no allegations as to, or relevant to, any claims against Sanofi and therefore requires no answer; to the extent Plaintiff purports to make allegations as to Sanofi, Sanofi denies each and every allegation set forth in paragraph 121 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

122. Paragraph 122 of the Complaint appears to contain no allegations as to, or relevant to, any claims against Sanofi and therefore requires no answer; to the extent Plaintiff purports to make allegations as to Sanofi, Sanofi denies each and every allegation set forth in paragraph 122 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

123. Paragraph 123 of the Complaint appears to contain no allegations as to, or relevant to, any claims against Sanofi and therefore requires no answer; to the extent Plaintiff purports to make allegations as to Sanofi, Sanofi denies each and every allegation set forth in paragraph 123 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

124. Denies each and every allegation set forth in paragraph 124 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

125. Denies each and every allegation set forth in paragraph 125 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein, and affirmatively states that if there were any merit to the claims alleged herein as to Sanofi, it would neither be impractical nor impossible for the Plaintiff to allege specifically its claims as to Sanofi, which Plaintiff has entirely failed to do.

126. Denies each and every allegation set forth in paragraph 126 of the Complaint as to Sanofi, denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein, and affirmatively states that plaintiff's obligation to provide adequate notice of the allegations against Sanofi cannot be met by conclusory allegations that Defendants should know what the case is about.

## **CLAIMS**

### **COUNT ONE -FRAUDULENT MISREPRESENTATION**

127. Sanofi repeats and incorporates by reference its responses to numbered paragraphs 1 through 126 above.

128. Denies each and every allegation set forth in paragraph 128 of the Complaint as to Aventis, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

129. Denies each and every allegation set forth in paragraph 129 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

130. Denies each and every allegation set forth in paragraph 130 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

**COUNT TWO - FRAUDULENT SUPPRESSION**

131. Sanofi repeats and incorporates by reference its responses to paragraphs 1 through 130 above.

132. Denies each and every allegation set forth in paragraph 132 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

133. Denies each and every allegation set forth in paragraph 133 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

134. Denies each and every allegation set forth in paragraph 134 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

**COUNT THREE - WANTONNESS**

135. Sanofi repeats and incorporates by reference its responses to paragraphs 1 through 134 above.

136. Denies each and every allegation set forth in paragraph 136 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

137. Denies each and every allegation set forth in paragraph 137 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

138. Denies each and every allegation set forth in paragraph 138 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

139. Denies each and every allegation set forth in paragraph 139 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

**COUNT FOUR -UNJUST ENRICHMENT**

140. Sanofi repeats and incorporates by reference its responses to numbered paragraphs 1 through 139 above.

141. Denies each and every allegation set forth in paragraph 141 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

142. Denies each and every allegation set forth in paragraph 142 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

143. Denies each and every allegation set forth in paragraph 143 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

144. Denies each and every allegation set forth in paragraph 144 of the Complaint as to Sanofi, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding other parties set forth therein.

Sanofi further denies that plaintiff is entitled to a judgment or any other relief requested in their section entitled "PRAYER FOR RELIEF" and unnumbered "WHEREFORE" paragraph following paragraph 144 of the Complaint.

### **DEFENSES**

By alleging the matters set forth below, Sanofi does not allege or admit that it has the burden of proof and/or the burden of persuasion with respect to any of these matters or that plaintiff is relieved of its burdens to prove each and every element of its claims and the damages, if any, to which it is entitled. As and for its affirmative defenses, Sanofi alleges as follows:

#### **FIRST AFFIRMATIVE DEFENSE**

1. Plaintiff fails to state a claim against Sanofi upon which relief may be granted.

#### **SECOND AFFIRMATIVE DEFENSE**

2. Plaintiff's claims are barred, in whole or in part, by the political question and separation of powers doctrines.

#### **THIRD AFFIRMATIVE DEFENSE**

3. Plaintiff has no standing or capacity to bring some or all of the claims raised in this suit to recover Medicaid expenditures or to seek injunctive relief.



**FOURTH AFFIRMATIVE DEFENSE**

4. Plaintiff has not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of Sanofi as alleged in the Complaint.

**FIFTH AFFIRMATIVE DEFENSE**

5. To the extent plaintiff obtains recovery in any other case predicated on the same factual allegations, plaintiff is barred from seeking recovery against Sanofi based on the Complaint pursuant to the doctrines of res judicata and collateral estoppel, and the prohibition on double recovery for the same injury.

**SIXTH AFFIRMATIVE DEFENSE**

6. Plaintiff's claims are barred, in whole or in part, by the First Amendment to the United States Constitution and the analogous provisions of the Constitution of the State of Alabama.

**SEVENTH AFFIRMATIVE DEFENSE**

7. Plaintiff's claims are barred, in whole or in part, by the filed rate doctrine.

**EIGHTH AFFIRMATIVE DEFENSE**

8. Plaintiff's claims are barred, in whole or in part, to the extent that plaintiff has released, settled, entered into an accord and satisfaction or otherwise compromised its claims.

**NINTH AFFIRMATIVE DEFENSE**

9. Any and all actions taken by Sanofi with respect to any of the matters alleged in the Complaint were taken in good faith and in accordance with established industry practice.

**TENTH AFFIRMATIVE DEFENSE**

10. Plaintiff's claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal



Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated thereunder.

**ELEVENTH AFFIRMATIVE DEFENSE**

11. Plaintiff's claims are preempted by the dormant Commerce Clause of the United States Constitution.

**TWELFTH AFFIRMATIVE DEFENSE**

12. Plaintiff's claims against Sanofi are barred because Sanofi has complied with all applicable regulations of the federal and state governments.

**THIRTEENTH AFFIRMATIVE DEFENSE**

13. Plaintiff's claims against Sanofi are barred, in whole or in part, by the applicable statutes of limitations and repose, and by the doctrines of laches, estoppel and waiver.

**FOURTEENTH AFFIRMATIVE DEFENSE**

14. Plaintiff's claims are barred, in whole or in part, because they violate Sanofi's rights under the Due Process and *Ex Post Facto* clauses of the United States Constitution, as well as the Constitution of the State of Alabama, insofar as plaintiff seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.

**FIFTEENTH AFFIRMATIVE DEFENSE**

15. Sanofi's statements or actions were not the proximate cause or cause in fact of any injury to or alleged loss by plaintiff.

**SIXTEENTH AFFIRMATIVE DEFENSE**

16. To the extent that plaintiff attempts to seek equitable relief against Sanofi, it is not entitled to such relief because it has an adequate remedy at law.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

17. Plaintiff's claims against Sanofi for injunctive relief were mooted by the passage of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

**EIGHTEENTH AFFIRMATIVE DEFENSE**

18. Plaintiff's claims for injunctive relief against Sanofi are barred by the doctrines of *in pari delicto* and/or unclean hands.

**NINETEENTH AFFIRMATIVE DEFENSE**

19. Plaintiff's claims against Sanofi are barred, in whole or in part, due to its failure to join indispensable parties.

**TWENTIETH AFFIRMATIVE DEFENSE**

20. Plaintiff's claims against Sanofi are barred, in whole or in part, because it has suffered no damages as a result of the matters alleged in the Complaint.

**TWENTY-FIRST AFFIRMATIVE DEFENSE**

21. Plaintiff's claims are barred, in whole or in part, because any injuries sustained by plaintiff were the result of its own conduct or the intervening or superceding conduct of third parties.

**TWENTY-SECOND AFFIRMATIVE DEFENSE**

22. Plaintiff's claims against Sanofi for damages are barred, in whole or in part: (1) because it failed to mitigate its damages, and its failure to mitigate damages should proportionately reduce the recovery of plaintiff and the allocation of any fault, if any exists, attributable to Sanofi; (2) because it would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint; (3) by the doctrine of consent and/or ratification to the extent that plaintiff has paid for products manufactured, marketed and sold by Sanofi after the

filing of plaintiff's original Complaint; and (4) because they are speculative and remote and because of the impossibility of ascertaining and allocating of those alleged damages.

**TWENTY-THIRD AFFIRMATIVE DEFENSE**

23. Sanofi is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by plaintiff, with respect to the same alleged injuries.

**TWENTY-FOURTH AFFIRMATIVE DEFENSE**

24. Any damages recovered by the plaintiff from Sanofi must be limited by the applicable statutory ceilings on recoverable damages, including without limitation, Alabama Code 6-11-21.

**TWENTY-FIFTH AFFIRMATIVE DEFENSE**

25. Plaintiff fails to allege facts or a cause of action against Sanofi sufficient to support a claim for compensatory damages, attorneys' fees and/or legal fees, or any other relief.

**TWENTY-SIXTH AFFIRMATIVE DEFENSE**

26. To the extent punitive damages are sought, Plaintiff's punitive damages claims against Sanofi: (1) have no basis in law or fact; (2) are not recoverable because the allegations of the Complaint are legally insufficient to support a claim for punitive damages against Sanofi; (3) cannot be sustained because the laws regarding the standards for determining liability for and the amount of punitive damages fail to give Sanofi prior notice of the conduct for which punitive damages may be imposed and the severity of the penalty that may be imposed, and are void for vagueness in violation of Sanofi's Due Process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and the Constitution of the State of Alabama; (4) cannot be sustained because any award of punitive damages exceeding the limits authorized by the laws or other comparable laws would violate Sanofi's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would

be improper under the Constitution, common law and laws of the State of Alabama; (5) cannot be sustained because an award of punitive damages in this case, combined with any prior, contemporaneous, or subsequent judgments against Sanofi for punitive damages arising from the design, development, manufacture, fabrication, distribution, supply, marketing, sale, or use of Sanofi' products would constitute impermissible multiple punishments for the same wrong, in violation of Sanofi' Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would constitute double jeopardy in violation of the Constitution, common law, and statutory laws of the State of Alabama; (6) cannot be sustained because any award of punitive damages without the apportionment of the award separately and severally between or among the alleged joint tortfeasors, as determined by the alleged percentage of the wrong committed by each alleged tortfeasor, would violate Sanofi' Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution, common law, and public policies of the State of Alabama; and (7) cannot be sustained because any award of punitive damages, which are penal in nature, without according Sanofi the same protections that are accorded to all criminal defendants, including the protection against unreasonable searches and seizures, the privilege against self-incrimination, and the rights to confront adverse witnesses, a speedy trial, and the effective assistance of counsel, would violate Sanofi' rights guaranteed by the Fourth, Fifth, and Sixth Amendment as incorporated into the Fourteenth Amendment to the United States Constitution and would be improper under the Constitution, common law, and public policies of the State of Alabama.

#### **TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

27. To the extent punitive damages are sought, Plaintiff's claims for punitive damages against Sanofi cannot be sustained because an award of punitive damages by a jury that: (1) is

not provided constitutionally adequate standards of sufficient clarity for determining the appropriate imposition of, and the appropriate size of, a punitive damages award; (2) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment; (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part on the basis of invidiously discriminatory characteristics, including without limitation the residence, wealth, and corporate status of Sanofi; (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; (5) is not properly instructed regarding plaintiff's burden of proof with respect to each and every element of a claim for punitive damages; and (6) is not subject to trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards, would violate Sanofi' Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution, and would be improper under the Constitution, common law, and public policies of the State of Alabama.

#### **TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

28. To the extent punitive damages are sought, Plaintiff's claims for punitive damages against Sanofi cannot be sustained because an award of punitive damages that is subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount of punitive damages that may be imposed, would: (1) violate Sanofi' due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution; (2) violate Sanofi' right not to be subjected to an excessive award; and (3) be improper under the Constitution, common law, and public policies of the State of Alabama.

**TWENTY-NINTH AFFIRMATIVE DEFENSE**

29. Sanofi has affirmatively stated on its published price lists that the AWP, or similar term, reported on its lists was a suggested price that was not intended to reflect actual price to any customer, and since at least August 2001, Sanofi has not included AWP or any similar term on its published price lists. Accordingly, plaintiff is estopped from claiming to have been defrauded by virtue of any action by Sanofi.

**THIRTIETH AFFIRMATIVE DEFENSE**

30. Some or all of plaintiff's claims against Sanofi arise from plaintiff's failure to follow its federal and state statutory and regulatory obligation to properly establish appropriate reimbursement rates.

**THIRTY-FIRST AFFIRMATIVE DEFENSE**

31. Plaintiff's unjust enrichment claims are barred, in whole or in part, because Sanofi did not retain any money belonging to the State as a result of any alleged overpayments as required under Alabama law.

**THIRTY-SECOND AFFIRMATIVE DEFENSE**

32. Plaintiff's claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine to the extent that such claims are premised, in whole or in part, on alleged statements or conduct by Sanofi in judicial, legislative, or administrative proceedings of any kind or at any level of government.

**THIRTY-THIRD AFFIRMATIVE DEFENSE**

33. Plaintiff's claims against Sanofi are misjoined with plaintiff's claims against other defendants and must be severed.

**THIRTY-FOURTH AFFIRMATIVE DEFENSE**

34. Sanofi adopts by reference any additional applicable defense pled by any other defendant not otherwise pled. Additionally, Sanofi hereby gives notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserves its right to amend its answer to assert such defense.

WHEREFORE, defendant Sanofi-Synthelabo Inc. demands that: (1) the Complaint be in all respects dismissed as to it; (2) it be awarded its costs of defending this action, including its reasonable attorneys' fees; and (3) it be awarded such other and further relief as the Court may deem just and proper.

Dated: January 30, 2006

OF COUNSEL:

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Respectfully submitted,

/s/ Richard H. Gill  
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*Attorneys for Defendant  
Sanofi-Synthelabo Inc.*

**CERTIFICATE OF SERVICE**

I hereby certify that I have on this 30<sup>th</sup> day of January, 2006, electronically served a true and correct copy of the foregoing pleading on counsel of record by transmission to LNFS, pursuant to Case Management Order No. 2.

/s/ Richard H. Gill

Of Counsel